

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03659PC U:UA/MW	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/SE 96/00779	International filing date (day/month/year) 14.06.1996	Priority date (day/month/year) 16.06.1995	
International Patent Classification (IPC) or national classification and IPC ₆ G 01 N 33/543 // C 12 Q 1/68			
Applicant Landegren Ulf			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

 These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:
 - I ☒ Basis of the report
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 13.01.1997	Date of completion of this report 25.09.1997
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. 08-667 72 88	Authorized officer Carl-Olof Gustafsson Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE 96/00779

I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

☒ the international application as originally filed.

☐ the description, pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,
pages _____, filed with the letter of _____.

☐ the claims, Nos. _____, as originally filed,
Nos. _____, as amended under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,
Nos. _____, filed with the letter of _____.

☐ the drawings, sheets/fig _____, as originally filed,
sheets/fig _____, filed with the demand
sheets/fig _____, filed with the letter of _____,
sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE 96/00779

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-8</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-8</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-8</u>	YES
	Claims		NO

2. Citations and explanations

The present application pertains to an immunoassay and test kit involving several affinity reagents of which two are modified with crosslinkable compounds enabling the formation of a crosslink between two reagents only when they are bound proximal to each other on two epitopes on the analyte. Preferably, the crosslinkable compounds are complementary oligonucleotides.

The International Search Report revealed two documents relating to the state of the art. Chemtech, vol. 24, 1995, pp 24-29 refers to the immuno-PCR method in which an oligonucleotide is used as a label with the ability to be amplified by the PCR method. The second document US5219734 refers to a method involving photoligation of polynucleotide probes which are allowed to ligate substantially contiguous ligands together on a target template (column 1, lines 5-11).

The present invention may thus seem to be a simple combination of these two known techniques and therefore would lack an inventive step. However, the fact that they have been available for several years in these fast evolving fields without being combined is a clear indication for the presence of an inventive step. Furthermore, the unexpected improvement achieved by linking the two reactants, and thereby reducing the effects of non-specific entrapment of reagent on the solid phase (see the description p. 2-3), is a strong indication for the presence of an inventive step.

Accordingly, the criteria of novelty, inventive step and industrial applicability are fulfilled for claims 1-8.

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(PCT Article 36 and Rule 70)

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- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 13.01.1997	Date of completion of this report 25.09.1997
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Telex 17978 PATOREG-S Facsimile No. 08-667 72 88	Authorized officer Carl-Olof Gustafsson Telephone No. 08-782 25 00

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE 96/00779

I. Basis of the report

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- ☒ the international application as originally filed.
- ☐ the description, pages _____, as originally filed,
 pages _____, filed with the demand,
 pages _____, filed with the letter of _____,
 pages _____, filed with the letter of _____.
- ☐ the claims, Nos. _____, as originally filed,
 Nos. _____, as amended under Article 19,
 Nos. _____, filed with the demand,
 Nos. _____, filed with the letter of _____,
 Nos. _____, filed with the letter of _____.
- ☐ the drawings, sheets/fig _____, as originally filed,
 sheets/fig _____, filed with the demand
 sheets/fig _____, filed with the letter of _____,
 sheets/fig _____, filed with the letter of _____.

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/fig _____

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/SE 96/00779

V. Resoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-8</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-8</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-8</u>	YES
	Claims		NO

2. Citations and explanations

The present application pertains to an immunoassay and test kit involving several affinity reagents of which two are modified with crosslinkable compounds enabling the formation of a crosslink between two reagents only when they are bound proximal to each other on two epitopes on the analyte. Preferably, the crosslinkable compounds are complementary oligonucleotides.

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Accordingly, the criteria of novelty, inventive step and industrial applicability are fulfilled for claims 1-8.

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark
Office
(Box PCT)
Crystal Plaza 2
Washington, DC 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 03 February 1997 (03.02.97)	
International application No. PCT/SE96/00779	Applicant's or agent's file reference P03659PL
International filing date (day/month/year) 14 June 1996 (14.06.96)	Priority date (day/month/year) 16 June 1995 (16.06.95)
Applicant LANDEGREN, Ulf	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

13 January 1997 (13.01.97)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Marie-José Devillard

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